

REMARKS/ARGUMENTS

Claims 1 to 15 are pending in the present patent application. Claim 16 has been cancelled. In view of the following remarks, reconsideration and withdrawal of the requirement for restriction ("Requirement") which is the subject of the Action are requested respectfully.

Discussion of the Requirement

The Action requires applicant to select one of the following three groups of allegedly patentably distinct inventions for examination.

- I. Claims 1 to 5 and 7, drawn to a topical pharmaceutical compositions;
- II. Claims 6 and 8, drawn to processes for preparing a composition;
- III. Claims 8 and 9, drawn to methods for treating hyperproliferative disorders.

Although applicant submits respectfully that the Requirement is improper, applicant elects provisionally the claims of Group I.

PCT Rule 13.1 states clearly that restriction is not required unless the inventions lack unity with regard to the common technical feature which is patentable over the prior art. Applicant submits respectfully that the common technical feature of the present invention is patentable over the prior art. Accordingly, the inventions presented in Groups I, II and III, while distinct, do not lack unity and thus should not be subject to restriction.

The common technical feature of the present inventions is a solid pharmaceutical composition suitable for oral delivery comprising at least one pharmacologically active agent, pharmaceutically acceptable inactive excipients, and a micronized delivery agent for said active agent (*see, e.g.*, claim 1). Applicant submits respectfully that this common technical feature is patentable over U.S. Patent No. 5,866,536 to Leone-Bay et al. ("Leone-Bay"). Leone-Bay does not disclose the present common technical feature. Further a person skilled in the art would not be motivated to modify Leone-Bay in such a way as to produce the presently claimed common technical feature.

In particular, Leone-Bay discloses compositions comprising at least one pharmacologically active agent, and at least one of Compounds I to CXXIII as delivery agents (*see Col. 2, lines 41 to 47*). Leone-Bay, however, does not disclose a micronized form of such delivery agents, or that the use of micronized delivery agents unexpectedly improves the absorption of the active agent into the blood stream (*see Specification at [0052]*). As such, the disclosure of Leone-Bay as a whole does not provide a reason or suggestion to one of ordinary skill in the art to modify the compositions disclosed therein by micronizing the delivery agent. As the inventions presented in Groups I, II, and III do not lack unity, a search and examination of all of the presently pending claims is requested respectfully.

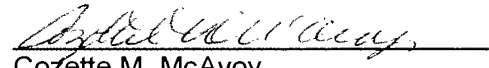
Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Action of record. If there are any issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney.

It is hereby requested that the term to respond to the Action of October 5, 2007 be extended pursuant to 37 C.F.R. § 1.136(a) for one (1) month, from November 5, 2007 to December 5, 2007. The Commissioner is hereby authorized to charge any fees required to Deposit Account No. **19-0134** in the name of Novartis.

Respectfully submitted,

Novartis Pharmaceuticals Corp.
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-9273


Cozette M. McAvoy
Attorney for Applicants
Reg. No. 60,457

Date: *16th November 2007*